Radiation Safety Committee Standard Operating Procedure	**Schedule of Meetings**

Schedule The Radiation Safety Committee (RSC) will schedule routine meetings each calendar quarter, on the third Thursday of February, May, August, and November.

Special meetings can be called by the Chair, as required.

Time Meetings will start at 8:00 am and end at approximately 11:30 am.

Location Meetings will be held at the following address:

George Washington Carver Building
5601 Sunnyside Avenue
Beltsville, MD 20705

Proposed Agenda A proposed agenda will be developed by the Chair and sent to the members and alternates prior to the meeting, Additional agenda items can be added by contacting the Chair, RSC.

Schedule Changes All Committee members will be notified of changes to the routine schedule at least two (2) weeks prior to the scheduled meeting date.

Approved:

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Chair, Radiation Safety Committee

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Radiation Safety Committee Standard Operating Procedure	**Membership**

General Each Agency having personnel using radioactive materials or radiation emitting equipment will be represented on the Radiation Safety Committee (RSC). The following Agencies are currently represented:

Agricultural Research Service	(ARS)
Animal & Plant Health Inspection Service	(APHIS)
Natural Resource Conservation Service	(NRCS)
Forest Service	(FS)
Food Safety Inspection Service	(FSIS)
Grain Inspection, Packers & Stockyards Administration	(GIPSA)
Agricultural Marketing Service	(AMS)

Agency Rep. The Chief Operating Official of each Agency listed above will nominate a qualified individual to serve as a member of the RSC. This individual will serve as the Agency's point of contact for matters relating to the USDA Radiation Safety Program.

An alternate will also be nominated to represent the Agency in the absence of the member.

USDA Management Rep. The Director, Safety and Health Management Division, will serve as a member of the RSC. This member serves as the USDA management representative to the RSC.

ARS Management Rep. The Associate Deputy Administrator for Administrative Management, Agricultural Research Service (ARS), will serve as a member of the RSC. This member serves as the ARS management representative to the RSC.

USDA RSO The USDA Radiation Safety Officer will serve as a member of the RSC.

Technical Rep.

In addition to the members indicated above, the Chair of the RSC will solicit additional members (and alternates) to provide technical expertise which may include, but is not limited to, the following areas:

Human Use Research
Biotechnology Research
Irradiator Use
Nuclear Gauge Use
Animal Research

Nomination & Approval

Agency management will forward the name and credentials of each nominee to the Chair of the RSC for review and approval.

Nomination & Approval of the Chair

The Director, Safety and Health Management Division will, after consultation with the Members of the RSC and the Radiation Safety Officer, forward the name and credentials of the nominee for Chair of the RSC to the Assistant Secretary for Administration for review and approval.

Term of Membership

The term of the Committee assignment is two (2) years.

Membership may serve multiple terms, not to exceed six (6) years continuous service.

Members must be renominated for each term.

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Chair, Radiation Safety Committee

Approved:

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Radiation Safety Committee Standard Operating Procedure	**Quorum and Voting**

Quorum

A quorum exists at any meeting of the Radiation Safety Committee (RSC) when at least one-half of the members, or in the absence of a member, their alternate, are present.

Voting on Motions

Motions and general Committee business is approved upon the approval of more than one-half of the members present at any meeting.

General Committee business requiring approval of the members sent out by mail or by facsimile will be approved upon the approval of more than one-half of the membership of the RSC.

Voting on Human Use Research

Motions to approve a human use research protocol requires the unanimous approval of the members (or their alternates).

Voting on Field Use Research

Motions to approve a research protocol involving the application of radioactive materials to a field or other outdoor area where there is a potential for release of the materials to the environment requires the approval of more than one-half of the membership of the RSC (or their alternates).

Approved:

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Chair, Radiation Safety Committee

_____

Date

Radiation Safety Committee Standard Operating Procedure	**Member Qualifications**

Members Nominated as Agency Rep.

Members (and Alternates) nominated as an Agency's representative to the Radiation Safety Committee (RSC) must hold a position in Headquarters, or report directly to a high-level Agency official, or must have training or experience in the use of radioactive materials or radiation emitting equipment, or must have e experience in the management of individuals whose assignments require the use of radioactive materials or radiation emitting equipment.

Members Nominated as Technical Rep.

Members (and Alternates) nominated as technical representatives to the RSC must have documented education and experience in the area for which they were selected.

Chair

The Chair of the RSC must have training and experience in at least one technical area involving the use of radioactive materials or radiation emitting equipment, and must have experience in the management of individuals whose assignments require the use of radioactive materials or radiation emitting equipment.

In addition, the Chair must attend a comprehensive 1-week radiation safety program management course during the first year of the appointment.

Approved:

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Chair, Radiation Safety Committee

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Date

Radiation Safety Committee Standard Operating Procedure	**Enforcement Actions**

Background The Radiation Safety Committee (RSC) has the delegated authority to approve the use of radioactive materials and radiation emitting devices under the terms of License Numbers 19-00915-03 and 19-00915-06 issued to the Department by the Nuclear Regulatory Commission (NRC). Retention of approval to use radioactive materials and radiation emitting devices by an individual is contingent upon adherence to applicable NRC regulations and USDA policies. The following guidelines will be followed when an approved user violates regulations of conditions of use.

Major Major violations are defined as those that involve actual or potential excessive radiation exposure to personnel, the general public or the environment, or willful and repeated negligence, such as the loss of radioactive material, or improper use of radioactive materials or devices in such a manner as to lead to potential injury or liability. These violations are comparable to Level I, II, and III violations of NRC regulations as stated in 10 CFR 2, Appendix C.

The following are examples of major violations:

- operating conditions that present an imminent danger of human exposure;
- significant deviation from an approved protocol;
- failure to correct a prior violation;
- transfer of radioactive materials or radiation emitting devices to an unapproved individual;
- act of negligence that leads to human exposure or environmental release;
- act of negligence that leads to the loss of control or loss of security of radioactive material or radiation emitting devices.

Enforcement Actions for Major Violations

The following enforcement actions are available to the Radiation Safety Committee (RSC):

- issuing a written warning to the Permit Holder or user;
- requiring additional training or certification;
- requiring a change in a user's protocol or in location procedures to prevent a reoccurrence of the violation;
- temporary suspension of approval to use radioactive materials or radiation emitting devices pending the findings of an investigation;
- permanent suspension of a user's authorization to use radioactive materials or radiation emitting devices pending the findings of an investigation;

Note: The findings of the investigation may be referred to line management for appropriate action if the violations involve a flagrant disregard for r regulations or safe operating procedures

Minor Violations

Minor violations are administrative and procedural deficiencies that are less serious than major violations, but which can become serious if left uncorrected. These violations are comparable to Level IV and V violations of NRC regulations.

The following are examples of minor violations:

- failure to maintain proper survey or personnel exposure records;
- failure to wear personal monitoring devices when required;
- failure to submit required bioassay results or samples;
- failure to return radioisotope receipt, use or disposal forms; and
- failure to perform required laboratory surveys.

Enforcement Actions for Minor Violations

The following enforcement actions are available to the RSC:

First violation: Written notification of violation to the responsible user, Location Radiation Protection Officer, and Agency Radiation Safety Program Coordinator.

Enforcement Actions for Minor Violations (Con't)	Second violation:	Written notification of violation to the responsible user, Location Radiation Protection Officer, and location management and Agency Radiation Safety Program Coordinator..
	Third violation:	Written notification of violation to the responsible user, Location Radiation Protection Officer, and location management and Agency Radiation Safety Program Coordinator..
		Potential suspension of authorization to use radioactive materials or radiation emitting devices, based on proposed corrective actions.
	Fourth violation:	Escalation of severity level to major violation status with appropriate enforcement actions.

Implementation of Enforcement Actions

A preliminary determination of the severity level will be made by the . USDA Radiation Safety Officer and the Chair of the Enforcement Subcommittee.

A meeting of the Enforcement Subcommittee will be held as soon as practical to review major violations and third and fourth minor violations. The Enforcement Subcommittee will determine and recommend actions that are appropriate for the nature and circumstances of the violation.

The Chair, RSC, after concurring with the enforcement recommendations, will implement the enforcement actions.

The Location Radiation Protection Officer and location management will insure that enforcement actions are implemented at the location level.

The RSC will review the enforcement actions at the next scheduled meeting to ratify or modify the actions as the final authority.

Reinstatement and Appeals

A suspended individual must apply for reinstatement of approval to use radioactive materials or radiation emitting devices after the conditions of the enforcement action are satisfied.

The Enforcement Subcommittee will review the request to determine if the conditions of the enforcement actions have been adequately satisfied.

The Chair, RSC, will reinstate the approval after concurring with the recommendation of the Enforcement Subcommittee.

An individual may appeal recommendations of the Enforcement Subcommittee and actions of the Chair, RSC, and has the right to be present at the deliberations on the case.

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Chair, Radiation Safety Committee

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Date

Approved:

Radiation Safety Committee Standard Operating Procedure	**Committee Training**

Background The independent assessment of the USDA Radiation Safety Program conducted in 1994 (Jupiter Report) identified training of Radiation Safety Committee members as an item for improvement. This recommendation was incorporated into the USDA Performance Improvement Plan.

Purpose The purpose of the training will be to provide the fundamental information needed by committee members to enable them to understand radiation safety related issues and problems regarding the subject area.

Training Areas The following training needs have been identified:

- Revisions in 10 CFR Part 20
- Theory and operation of Nuclear Density Gauges;
- Theory and operation of Electron Capture Detectors;
- Construction, operation and licensing of self-shielded irradiators;
- Radioactive materials use in biotechnology research
- Radioactive materials use in human research;
- Current issues in incineration of radioactive materials;
- Radiation Safety Staff procedures for issuing Use Permits; and
- Licensing issues in Type A Broad Scope Materials Licenses.
- Radioactive waste management

Additional areas may be included as the need is identified.

Imple-mentation	A 15-30 minute training session will be conducted during a regularly scheduled RSC meeting. For special topics, a separate training date will be scheduled. A training schedule for the next calendar year will be developed during the fourth quarterly committee meeting of each year.

Approved:

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Chair, Radiation Safety Committee

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Date

Radiation Safety Committee Standard Operating Procedure	**Reports Required from the Radiation Safety Staff**

General

As a part of the general radiation safety program oversight function assigned to the Radiation Safety Committee (RSC), certain administrative and management reports are to be submitted to the RSC by the USDA Radiation Safety Staff for their review at each committee meeting.

Quarterly Reports

The following reports will be submitted to the RSC on a quarterly basis:

- Inspections performed/Violations noted/Corrective actions taken
- Incidents and Accidents
- Permit actions completed and pending
- NRC licensing correspondence summary
- Over-due reports and correspondence from USDA locations
- Bioassay monitoring/Exposure incidents

Annual Reports

The following reports will be submitted to the RSC on an annual basis:

- RSS Staffing and Funding Plan
- Facility inspection schedule
- Summary of human use research and field studies

Approved

Radiation Safety Committee Standard Operating Procedure	**Agency Management Briefings**

Background The independent assessment of the USDA Radiation Safety Program conducted in 1994 identified communication with senior Agency management personnel as an item for improvement. This recommendation was incorporated into the USDA Performance Improvement Plan.

Recom-mendation Agency representatives to the USDA Radiation Safety Committee (RSC) should brief senior agency management personnel on an annual basis. This briefing should be documented.

If possible, representatives of field organizations as well as headquarters management should be included in these briefings.

Purpose The purpose of the communication is:

- to update agency management on significant issues involving the use of radioactive materials or radiation emitting equipment within the Agency; and
- to discuss changes in Federal or Departmental rules or regulations that impact the USDA Radiation Safety Program.

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Chair, Radiation Safety Committee

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Date

Examples The following are examples of the types of meetings that could be used for Agency Radiation Safety Program briefings:

Agricultural Research Service: Administrator's Council

Meetings typically involve the Agency Administrator, Headquarters administrator and program personnel, and Area Directors.

Animal & Plant Health Inspection Service: Management Team Meetings

Meetings typically involve the Agency Administrator, Deputy Administrators for program areas such as Plant Protection & Quarantine, International Services, etc. These meetings are held several times each year.

Forest Service: National Leadership Conferences

Meetings typically involve the Chief and staff, Regional foresters, Station Directors, Area Directors, and IITF Director.

Natural Resource Conservation Service

Routine communication have been established with the Deputy Chief for Management and Strategic Planning, who serves as the Designated Agency Safety and Health Officer.

Agricultural Marketing Service

After each USDA Radiation Safety Committee meeting, information regarding the meeting agenda and any actions affecting the Agency will be included in the Science Division's weekly report to the Agency Administrator.

USDA RADIATION SAFETY COMMITTEE HANDBOOK

Approved:

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Chair, Radiation Safety Committee

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Date

United States Department of Agriculture	Radiation Safety Program	Standard Operating Procedure
Radiation Safety Program Organization		

Introduction This document describes the management organizations for the US Department of Agriculture (USDA) Radiation Safety Program

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Radiation Safety Policy

The radiation safety policy of the USDA is found in Departmental Regulation 4400. This policy states that:

! The U.S. Department of Agriculture (USDA) will comply with all applicable Federal, state and local laws and regulations governing the use of radioactive materials and equipment that produces ionizing radiation.

! The USDA will protect its employees, the public, and the environment from the risk of hazards which might be caused by the use of such materials and equipment.

Radioactive Materials The US Department of Agriculture (USDA) holds two licenses issued by the US Nuclear Regulatory Commission (NRC).

Licenses

! License Number 19-00915-03 is a broad scope license authorizing the use of radioactive materials for research and development, in gauging and measuring devices, in field applications, and for research studies in humans at locations throughout the United States, as approved by the Department's Radiation Safety Committee (RSC).

! License 19-00915-06 authorizes the use of cobalt-60 and cesium-137 in self-shielded irradiators as approved by the Radiation Safety Committee.

The USDA is inspected each year by the NRC to verify compliance with these licenses and the regulations on which they are based.

Quality Assurance Program

The USDA holds an approved fabricators and transporters Quality Assurance Program issued by the NRC for irradiator shipping packages.

Delegation of Authority

The responsibility for the USDA Radiation Safety Program (RSP) is delegated to the Assistant Secretary for Administration.

United States Department of Agriculture	Radiation Safety Program	Standard Operating Procedure
Radiation Safety Staff Organization		

Introduction This document describes the management organization of the US Department of Agriculture (USDA) Radiation Safety Staff

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Background In January 1994 an independent assessment of the USDA Radiation Safety Program (the Jupiter Report) recommended that the program be located with the Assistant Secretary for Administration to coordinate all Departmental safety programs and elevate the Radiation Safety Program within the Department.

On February 22, 1995, the transfer of the Radiation Safety Staff (RSS) to the Safety and Health Management Division, Office of Personnel was approved.

Radiation Safety Staff Functions

The Radiation Safety Staff is organized into two functional areas.

- **Permit Operations Section**

The Permit Operations Section is responsible for all administrative activities relating to the issuance and maintenance of user permits

- **USDA Mission Area Health Physics Support**

The health physicists within RSS are responsible for providing technical and management assistance to the Agencies within a specific USDA Mission Area.

In addition, two temporary positions have been established.

- **Performance Improvement Plan (PIP) Coordinator**

The PIP Coordinator monitors and reviews all PIP activities to assure that they are performed in accordance with the implementation plan submitted to the Nuclear Regulatory Commission.

- **Computer Specialist**

The computer specialist maintains the Radiation Safety Program information systems used to issue user permits and provide management information, maintains the local area networks and implements electronic communication with field staff.

Radiation Safety Committee Standard Operating Procedure	**Annual Compliance and Program Audit**

Background The Radiation Safety Committee (RSC) has been delegated responsibility for the administration of radiation safety functions within the Department of Agriculture. The Radiation Safety Officer is delegated the day-to-day responsibility for the management and operation of the radiation safety program

The USDA has two licenses issued by the US Nuclear Regulatory Commission (NRC) which regulate the procurement, use, and disposal of radioactive materials within the

Department. In addition, USDA policy regulates the use of radiation emitting equipment through conformance with the guidance provided by the National council on Radiation Protection and Measurements (NCRP). The NRC conducts inspections of radioisotope use at field locations throughout the country and reviews the results of those inspections during its annual audit of the Radiation Safety Staff (RSS) activities. As part of its assessment process, the NRC reviews the USDA management commitment to radiation safety.

Audit Criteria

As a function of its management oversight, the USDA Radiation Safety Committee will perform routine audits of the Radiation Safety Staff. These audits will assess the following areas of operation:

- Program management;
- RSS compliance with NRC rules and regulations;
- RSS compliance with the NRC licenses and license conditions;
- RSS interaction with the Radiation Safety Committee;
- Effectiveness of communication with USDA field sites; and
- Understanding and implementation of radiation safety requirement at USDA field sites.

Program Management

The program management review will be conducted to assess the level of effort expended by the RSS in the routine performance of their duties. Data to be collected will include:

- Review of workload and program activity.
  - -Staffing level in FTE's (professional, technical, clerical)
  - -Number of USDA locations having active users
  - -Number of active users
  - -Number of applications processed (new, renewals, amendments, and terminations)

- Review of training needs of the RSS (professional, technical, clerical)

- Review of availability of regulatory guidance documents
  - -Current copies of Code of Federal Regulations, Titles 10, 21, 40, and 49 available
  - -US NRC regulatory guides and bulletins available
  - -NCRP, ICRP reports available as needed

- Review of RSS guidance documents
  - -Program forms are adequate and distributed to field
  - -Program guidance, use conditions, special procedures are adequate and distributed to field
  - -Licenses, NRC regulations, inspection correspondence distributed to field

- Review of office procedures
  - -Document tracking system adequate
  - -Filing system adequate

- Review of facility inspection scheduling
  - -System implemented to track inspections performed and their results
  - -System implemented to track facilities due for inspection
  - -Inspection schedule meets compliance requirements

- Review of RSS program database development
  - -Project management system in place to track system development
  - -Milestones for timely implementation are being met

Compliance with License Conditions

The following activities will be reviewed to assure compliance with US NRC license 19-00915-03 (Broad Scope):

- Sealed source leak testing program (Condition 12)
  - -Number of sources to be tested
  - -Method developed to assure testing on a six-month schedule
  - -Rate of field compliance

- Sealed source inventory (Condition 15)
  - -Inventory conducted on a six-month schedule
  - -Records maintained two years

- Quarterly laboratory surveys
  - -Method developed to assure field response
  - -Rate of field compliance

- Incineration of radioactive waste (Condition 19)
  - -Quarterly records submitted for each incinerator
  - -Ash analysis performed when required
  - -Compliance determination performed

- Human studies (Condition 20)
  - -Protocols available for review
  - -Summary lists isotopes to be used, names of physician/users, FDA RDRC review, length of study

- Permit approval process
  - -Status of application being processed
  - -Safety criteria used by reviewers

- Burial Sites (Condition 22)
  - -Listing of all sites available
  - -Monitoring records available

- Radioisotope inventory (Condition 23)
  - -Inventory summary complied for each location
  - -Summary below 10 CFR 30.72 limits
  - -Responsible User's inventory within RSC approved limits

Compliance with License Conditions (Con't)

The following activities will be reviewed to assure compliance with US NRC license 19-00915-06 (Irradiators):

- Irradiators
  - -Number of irradiators in service
  - -Current US NRC/DOT certification on file

-RSS QA program operational
-Incident log reviewed

Dosimetry Program Review

! Film badge program
-Number of badges distributed monthly
-Average dose received by USDA employees
-Maximum dose received
-Incident log reviewed

! Bioassay program
-Number of bioassays reported
-Estimated average dose from uptake
-Incident log reviewed

Survey and Laboratory Instruments

! Survey instruments
-All instruments operational
-Calibration current for each instrument
-Calibration certification available for review

! Laboratory instruments
-All instruments operational
-Calibration/QA records available

Field Compliance Review

To further assess the regulatory compliance within the Department, selected field sites will be visited to assess their implementation of radiation safety guidance.

Site visits will be scheduled as a follow-up to an inspection conducted by RSS. The site visit is not intended to duplicate the inspection. Rather it will assess the facility's ability to correct deficiencies noted, and will assess the facility's implementation and understanding of USDA radiation safety guidance.

Field Compliance Review, (Con't)

The following activities will be reviewed:

! Implementation of the Location Radiation Protection Officer (LRPO) program

by the facility

-LRPO performance standards are implemented
-LRPO conducts periodic surveys of permitted users

! Knowledge of the LRPO and the Responsible Users of license documents and RSS policy

-Current copies of USDA license, NRC regulations and license correspondence available. Knowledge of the Responsible Users regarding radiation safety practices, USDA license and approval conditions for radioisotope use

! Records management for the LRPO and the Responsible Users

-Copies of RSC approval documents, laboratory surveys, inventory available for review
-Documentation of employee training available for review
-LRPO maintains necessary files and records

! Radioactive waste management practices

-Disposal records available for review
-Disposal location orderly

! Site radiation safety training program

-Training program meets current standards
-Current employees have been trained

! Interaction between RSS and facility management

Evaluation Worksheet A Field Radiation Safety Program Evaluation Worksheet is attached to this document.

Approved:

_____
Chair, Radiation Safety Committee

_____

Radiation Safety Committee Standard Operating Procedure	**Field Radiation Safety Program Evaluation Worksheet**

Evaluation Date: _____

Facility: _____

Location: _____

Program Management

	(Circle One)	
1. Location Radiation Protection Officer has been identified?	Yes	No
2. LRPO performance standards have been implemented?	Yes	No
3. Facility director is briefed on radiation safety by LRPO?	Yes	No
4. LRPO has received radiation safety training?	Yes	No

LRPO Program Management

5. LRPO has dedicated files for radiation safety program information?	Yes	No
6. LRPO has file copies of permits and correspondence for Responsible Users?	Yes	No
7. LRPO has NRC required documented for posting and reading?	Yes	No
8. LRPO has copies of the USDA license and correspondence?	Yes	No
9. LRPO maintains copies of radioisotope inventory and waste disposal records for the facility?	Yes	No
10.LRPO is knowledgeable about the radioisotope use at the facility?	Yes	No
11.LRPO is knowledgeable about the radiation emitting devices in the facility?	Yes	No

Facility Training

12.Facility has routine training for Responsible Users?	Yes	No
13.Facility has routine training for Associate Users and Laboratory staff?	Yes	No
14.Facility has routine training for Ancillary Staff?	Yes	No
15.Records are maintained of training?	Yes	No

Interactions with Radiation Safety Staff

16. Does facility management know the Director, RSS by name? Yes No
17. Do the Responsible Users generally know the name of the RSS health physicist assigned to their facility? Yes No
18. Is the RSS staff seen as responsive to facility problems? Yes No
19. Is the RSS staff timely in permit reviews? Yes No
20. Other facility concerns: _____

_____
_____
_____
_____
_____